

AMENDMENT TO THE CLAIMS

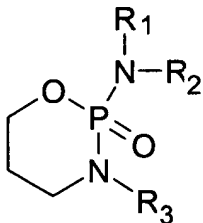
Please amend the claims as follows:

Claims 1-26 (cancelled).

27. (new) A process for preparation of a low toxicity, stable oxazaphosphorine-containing composition comprising an oxazaphosphorine antineoplastic, mesna, and an etherified β -cyclodextrin; the process comprising the steps of:

- i) adding the oxazaphosphorine antineoplastic to an aqueous solution of an etherified β -cyclodextrin;
- ii) adding mesna as such or as an aqueous solution optionally containing an etherified β -cyclodextrin to the oxazaphosphorine solution of step (i); and
- iii) mixing the resultant aqueous solution and, optionally, making up the volume with water.

28. (new) A process as claimed in Claim 27, wherein the oxazaphosphorine antineoplastic is of the formula:



in which at least two of R₁, R₂, and R₃ independently are 2-chloroethyl and the remaining R radical is hydrogen.

29. (new) A process as claim in claim 28, wherein R₁ = R₂ = chloroethyl, R₃ = hydrogen, and the oxazaphosphorine antineoplastic is Cyclophosphamide.

30. (new) A process as claimed in Claim 28, wherein R₁ = R₃ = chloroethyl, R₂ = hydrogen, and the oxazaphosphorine antineoplastic is Ifosfamide.

31. (new) A process as claimed in Claim 27, wherein the etherified β -cyclodextrin used is Hydroxypropyl Beta Cyclodextrin.

32. (new) A process as claimed in Claim 31, wherein the molar substitution of Hydroxypropyl Beta Cyclodextrin is from about 0.5 to about 1.2.

33. (new) A process as claimed in Claim 27, wherein the oxazaphosphorine antineoplastic content of the composition is from about 1 mg/ml to about 1000 mg/ml.

34. (new) A process as claimed in Claim 33, wherein said oxazaphosphorine antineoplastic content is from about 25 mg/ml to about 750 mg/ml.

35. (new) A process as claimed in Claim 34, wherein said oxazaphosphorine antineoplastic content is from about 50 mg/ml to about 500 mg/ml.

36. (new) A process as claimed in Claim 35, wherein said oxazaphosphorine antineoplastic content is about 50 mg/ml.

37. (new) A process as claimed in Claim 35, wherein said oxazaphosphorine antineoplastic content is about 500 mg/ml.

38. (new) A process as claimed in Claim 27, wherein the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 20:1 to about 1:2 on a weight basis.

39. (new) A process as claimed in Claim 38, wherein the ratio of oxazaphosphorine antineoplastic to mesna is in the range of about 10:1 to about 1:1 on a weight basis.

40. (new) A process as claimed in Claim 39, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10:2 on a weight basis.

41. (new) A process as claimed in Claim 39, wherein the ratio of oxazaphosphorine antineoplastic to mesna is 10:6 on a weight basis.

42. (new) A process as claimed in Claim 27, wherein the content of etherified β -cyclodextrin in the composition is about 1% to about 60% w/v.

43. (new) A process as claimed in Claim 42, wherein said etherified β -cyclodextrin content in the composition is about 2.5% to about 40% w/v.

44. (new) A process as claimed in Claim 43, wherein said etherified β -cyclodextrin content in the composition is about 5% to about 20% w/v.

45. (new) A process as claimed in Claim 27, wherein one or more conventional parenteral additives are incorporated into the aqueous solution of Claim 27 step (i) or Claim 27 step (ii) or in water used for making up the volume in Claim 27 step (iii).

46. (new) A process as claimed in Claim 27, wherein said mixture of resultant aqueous solutions is sterilized by filtering through a sterilizing grade filter.

47. (new) A process as claimed in Claim 46, wherein the filtrate from the sterilizing grade filter is aseptically filled into sterile containers and the filled containers are sealed.

48. (new) A process as claimed in Claim 27, wherein the mesna is present as the aqueous solution, and the aqueous solution of step (ii) contains the etherified β -cyclodextrin.

49. (new) A process as claimed in Claim 27, including in step (iii) the step of making up the volume with water.

50. (new) A stable oxazaphosphorine-containing composition obtainable or prepared by a process as claimed in Claim 27.

51. (new) The use of a stable oxazaphosphorine-containing composition as defined in Claim 50 in the manufacture of a medicament for the treatment of malignant disease.

52. (new) A method of treating a malignant disease comprising administering to a patient suffering said disease an effective amount of a sterile stable oxazaphosphorine-containing composition as defined in Claim 50.